Bone Growth Stimulators
Clinical Coverage Criteria

Overview

A bone growth stimulator is an adjunct intervention used to stimulate the body's natural bone healing process which may be impaired in some at-risk patients. Two types of bone growth stimulators currently exist: electrical and ultrasound.

Three forms of electrical bone growth stimulation devices are currently used: direct current electrical stimulation, capacitive coupling and pulsed electromagnetic fields (PEMF). Indications for use are based upon U.S. Food and Drug Administration (FDA) labeling for specific devices and evidence in the peer-reviewed published scientific literature.

Direct current electrical stimulation consists of cathodes connected to a power supply which also serves as an anode. These devices are surgically implanted with the cathode placed at the fusion site and the anode in the soft tissue. Direct current devices may or may not be removed following achievement of a solid fusion.

In contrast, capacitive coupling and PEMF are non-invasive techniques. Capacitive coupling consists of two electrodes placed on the skin over the fusion site and connected to an external generator. Patients are encouraged to use the stimulator as much as possible, up to 24 hours per day. PEMF consists of a treatment coil that is incorporated into a cast or placed directly on the skin over the fracture site. The coil produces a time varying magnetic field around the area of the desired fusion. Patients are generally instructed to wear PEMF devices for 3 to 8 hours per day (Resnick et al., 2005, Kaiser et al., 2014).

An ultrasound bone growth stimulator provides low-intensity pulsed ultrasound to the skin surface above fracture site. Exogen (Bioventus, LLC) is the only FDA-approved ultrasound bone healing device. Exogen (PMA P900009) is approved for the non-invasive treatment of established nonunions excluding skull and vertebra, and for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing. On December 19, 2019, Exogen received FDA approval for expanded indications for use to include adjunctive use in patients with internal or external fracture fixation hardware present, patients undergoing treatment for infection at the fracture site, and patients believed to have diminished bone quality.

A 2013 technology assessment on the use of Exogen for long bone fractures with nonunion or delayed union conducted by the National Institute for Health and Care Excellence (NICE) concluded that despite the absence of direct evidence on avoiding surgery, there was "some radiologic evidence of improved healing," the adoption of Exogen in the treatment of long bone fractures with nonunion was supported by the evidence. NICE concluded that the use of Exogen in the treatment of long bone fractures with delayed healing was not supported by the evidence.

Regarding the use of Eoxgen for the treatment of fresh fractures, a 2014 Cochrane review (Griffin et al., 2014) concluded that while a potential benefit of ultrasound for the treatment of acute fractures in adults cannot be ruled out, the currently available evidence is insufficient to support

the routine use in clinical practice. The publication of the TRUST trial (NCT00667849), a multicenter trial randomized sham-controlled trial of 501 patients with fresh tibial fractures cast doubt on the effectiveness of LIPUS for the treatment of fresh fractures (Busse et al., 2016). Busse et al. concluded that postoperative use of LIPUS after tibial fracture fixation does not accelerate radiographic healing and fails to improve functional recovery.

To best inform evidence-based patient care, it is desirable to compare competing therapies. There have been no comparative studies evaluating electrical stimulation versus ultrasound bone growth stimulators (Ebrahim et al., 2014).

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial

☒ Medicare Advantage

☒ MassHealth ACO

☒ NaviCare

☒ PACE

Fallon Health uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for Medicare Advantage, NaviCare and PACE plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

See Part II. below for coverage criteria for bone growth stimulators for Medicare Advantage, NaviCare and PACE plan members.

Prior authorization is required. Requests must be supported by documentation in the treating provider's medical records.

Part I. For commercial and MassHealth members

A noninvasive non-spinal electrical bone growth stimulator (HCPCS code E0747) is covered for the following indications:

- Nonunion of long bone fractures in skeletally mature patients without serious systemic disease who are not taking steroids or other immunosuppressants, or
- Congenital pseudoarthrosis.

A noninvasive spinal electrical bone growth stimulator (HCPCS code E0748) is covered for the following indications:

- Failed spinal fusion, where a minimum of 6 months has elapsed since the last surgery and serial radiographs confirm there is no evidence of progression of healing for 3 months prior to starting treatment with the bone growth stimulator, or
- As an adjunct to spinal fusion for patients at high-risk for pseudoarthrosis.*

An invasive electrical bone growth stimulator (CPT code 20975 is used to report the implantation of an electric bone growth stimulator and HCPCS code E0749 is used to report the device) is covered for the following indications:

- Nonunion of a long bone fractures, or
- As an adjunct to spinal fusion in patients at high risk for pseudoarthrosis* due to previously failed fusion at the same site, or for patients undergoing multiple-level spinal fusion involving 3 or more vertebrae, or
- As an adjunct to primary ankle or foot fusion in patients at high risk for pseudoarthrosis.*

The following criteria must also be met for noninvasive and invasive electrical bone growth stimulators:

- The patient is 20 years of age or older or demonstrates proof of skeletal maturity, and
- The fracture gap is < 1 centimeter, and
- For nonunion of long bone fractures, serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the bone growth stimulator, as demonstrated by a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

* Patient factors play a significant role with regards to pseudoarthrosis risk. High risk for pseudoarthrosis exists when:
- Previously failed fusion at the same site, OR
- Grade III or worse spondylolisthesis, OR
- Undergoing a multiple-level spinal fusion involving 3 or more vertebrae: e.g., L3-L5, L4-S1, etc.), OR
- Body mass index (BMI) of > 30 or who are greater than 50% over their ideal body weight, OR
- Diabetes, renal disease, or other metabolic diseases where bone healing is likely to be compromised or growth is poor, OR
- Nutritional deficiency/malnutrition, OR
- Severe anemia, OR
- Steroid therapy, OR
- Smoking, OR
- Alcohol consumption

An ultrasound bone growth stimulator (HCPCS code E0760) is covered for the treatment of established nonunions when all of the following criteria are met:
- The patient is 20 years of age or older or demonstrates proof of skeletal maturity, and
- The fracture is not of the skull or vertebrae, and
- The fracture is not tumor related, and
- The fracture is stable and well-aligned with a gap < 1 centimeter, and
- Serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the bone growth stimulator, as demonstrated by a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days, and
- The patient has failed at least one surgical or medical intervention for the treatment of the fracture.

Part II. Medicare Advantage, NaviCare and PACE plan members
The following coverage criteria are consistent with the **Medicare NCD for Osteogenic Stimulators (150.2)** and the **Noridian Healthcare Solutions, LLC, LCD for Osteogenesis Stimulators (L33796):**

A noninvasive, non-spinal electrical bone growth stimulator (HCPCS code E0747) is covered when any of the following criteria are met:
- Nonunion of a long bone (clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal) fracture* defined as radiographic evidence that fracture healing has ceased for three or more months prior to starting treatment with the bone growth stimulator, or
- Failed fusion of a joint other than in the spine where a minimum of 9 months has elapsed since the last surgery, or
- Congenital pseudoarthrosis.

* Nonunion of a long bone fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the bone growth stimulator, separated by a minimum of 90 days, each including multiple views of the fracture site, and with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

A noninvasive, spinal electrical bone growth stimulator (HCPCS code E0748) is covered when any of the following criteria are met:

- Failed spinal fusion where a minimum of 9 months has elapsed since the last surgery, or
- Following a multiple-level (3 or more vertebrae, e.g., L3-L5, L4-S1, etc.) spinal fusion surgery, or
- Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.

An invasive electrical bone growth stimulator (CPT code 20975 is used to report implantation of an electric bone growth stimulator and HCPCS code E0749 is used to report the device) is covered when any of the following criteria are met:

- Nonunion of a long bone (clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal) fracture defined as radiographic evidence that fracture healing has ceased for three or more months prior to starting treatment with the bone growth stimulator, or
- As an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed fusion at the same site or for those undergoing multilevel (3 or more vertebrae (e.g., L3-L5, L4-S1, etc.) fusion.

An ultrasonic bone growth stimulator (HCPCS code E0760) is covered only if all of the following criteria are met:

- Nonunion of a fracture documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied by a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs; and
- The fracture is not of the skull or vertebrae; and
- The fracture is not tumor related.

Exclusions

- Any use of Bone Growth Stimulators other than outlined in this policy.
- Concurrent use of electrical (invasive or noninvasive) and ultrasound bone growth stimulators is not covered.
- Use of an ultrasound bone growth stimulator for the treatment of a fresh fracture or delayed union is considered investigational.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

CPT code 20975 should be used to report the implantation of an electric bone growth stimulator (physician services) and HCPCS code E0749 should be used to report the implanted device.

CPT code 20974 and 20979 should be used to report noninvasive electric or ultrasound stimulation treatment performed by a physician to aid bone healing. It is not appropriate to report these codes for demonstration, measuring, and/or education related to an electric or ultrasound bone growth stimulation device.

Bone growth stimulators E0747, E0748 and E0760 are considered durable medical equipment.

Code	Description
20974	Electrical stimulation to aid bone healing; noninvasive (non-operative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive, (nonoperative)
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spinal

	applications
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted
E0760	Osteogenic stimulator, low intensity ultrasound, non-invasive

References

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2. Hayes Inc. Hayes Directory Electrical Bone Growth Stimulation, Invasive. Published June 13, 2018.
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Policy history

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06/15/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.